K132468

510(k) Summary

MRSA/SA ELITe MBG

OCT 17 2013

1.	Date:	August 5, 2013
2.	Submitter:	Epoch Biosciences 21720 23rd Dr SE, Suite 150 Bothell, WA 98021 USA
3.	Contact Person:	Debra K. Hutson Director, QA/RA, North America 21720 23rd Dr SE, Suite 150 Bothell, WA 98021 Phone: 425-482-5174 Fax: 425-482-5550 Email: d.hutson@elitechgroup.com
4.	Device Name: Device Class: Product Code: Regulation name: Panel: Regulation Number:	MRSA/SA ELITe MGB® Class II NQX Antimicrobial Susceptibility Test Powder 83 Microbiology 21 CFR 866.1640
5.	Predicate Device:	k112937 Epoch Biosciences MRSA/SA ELITe MGB®
6.	Intended Use	MRSA/SA ELITe MGB® is a qualitative *in vitro* diagnostic test for the direct detection of *Staphylococcus aureus* (SA) and methicillin-resistant *Staphylococcus aureus* (MRSA) using DNA purified from nasal swabs. MRSA/SA ELITe MGB® is intended to aid in the prevention and control of MRSA infections in healthcare settings. It is not intended to diagnose, guide or monitor MRSA infections, or provide results of susceptibility to oxacillin/methicillin. A negative result does not preclude MRSA/SA *(Staphylococcus aureus)* nasal colonization. Concomitant cultures are necessary to recover organisms for epidemiological typing or for further susceptibility testing.

Special conditions for use statement(s):
Prescription Use Only.

7. **Device Description**

MRSA/SA ELITe MGB® is a real-time, multiplex polymerase chain reaction (PCR) assay for the in vitro qualitative detection of MRSA and SA DNA extracted from human nasal swab samples. In this system, sample preparation and amplification/real-time detection are completed on separate instruments. Sample processing is completed on the bioMérieux NucliSENS® easyMAG® instrument with bioMérieux NucliSENS Nucleic Acid Extraction Reagents according to the manufacturer's instructions. Following processing, the extracted sample is placed in the well of a 96 well plate to which "monoreagent" is added. The monoreagent contains the primers and probes for the genes of interest and the internal control combined with master mix. The assay is performed on an Applied Biosystems 7500 FAST Dx System that consists of the 7500 FAST Dx instrument, a personal computer, 96-well plates and seals. The total system run time is 150 minutes consisting of 60 minutes for sample processing and about 90 minutes for the real time amplification and detection steps. The instrument never comes into contact with any fluids within the 96-well plate. Each disposable plate is intended to test up to 96 samples, controls or any mixture thereof. The 96-well plates are not re-usable and are specific to the system. The kit contains enough reagents for 100 reactions. One positive and one negative control are required for each PCR run; a Negative Processing Control and a Positive Processing Control are recommended to be run in each extraction run. The design of the assay includes systems to identify both the gene responsible for methicillin resistance and for a conserved portion of a gene unique to *S. aureus*. Thus, for a true "MRSA," both targets will be identified in roughly equal proportions. Results are determined by using an algorithm that compares output, Cq, from the cycler (called Ct in the output from the cycler.) The algorithm is implemented for automatic results determination by analyzing the output Cq with ELITe MGB® software.

8. **Substantial Equivalence Information - Assay (reagent)**

1. Predicate Device Name
   Epoch Bioscience MRSA/SA ELITe MGB®
2. k112937
3. Comparison with predicate

Similarities

Parameter	Test System Epoch Bioscience MRSA/SA ELITe MGB® using ELITe MGB® Software for data analysis	Predicate Device Epoch Bioscience MRSA/SA ELITe MGB® k112937
Intended Use / Indication for Use	MRSA/SA ELITe MGB® is a qualitative *in vitro* diagnostic test for the direct detection of *Staphylococcus aureus* (SA) and methicillin-resistant *Staphylococcus aureus* (MRSA) using DNA purified from nasal swabs. MRSA/SA ELITe MGB® is intended to aid in the prevention and control of MRSA infections in healthcare settings. It is not intended to diagnose, guide or monitor MRSA infections, or provide results of susceptibility to	Same

Parameter	Test System Epoch Bioscience MRSA/SA ELITe MGB® using ELITe MGB® Software for data analysis	Predicate Device Epoch Bioscience MRSA/SA ELITe MGB® k112937
	oxacillin/methicillin. A negative result does not preclude MRSA/SA (*Staphylococcus aureus*) nasal colonization. Concomitant cultures are necessary to recover organisms for epidemiological typing or for further susceptibility testing.	
Mode of identification of *S. aureus*	Presence of conserved region in a *Staphylococcus aureus*-specific gene.	Same
Mode of detection for methicillin resistance	Presence of the *mecA* gene which is responsible for resistance to methicillin.	Same
Assay Format	Qualitative real-time polymerase chain reaction (PCR) assay using 3 forward primer, 3 reverse primers, and 3 fluorescent-labeled probes for the amplification and detection of *Staphylococcus aureus* (SA) and methicillin resistant *Staphylococcus aureus* (MRSA) DNA.	Same
Composition	**MRSA/SA ELITe MGB® PCR Mix** Tfi PCR Master Mix <0.01% MRSA/SA primers <0.01% Internal Control primers <0.01% MRSA/SA Fluorescent-labeled oligonucleotide probes <0.01% Internal Control Fluorescent-labeled oligonucleotide probe <0.01% Fluorescent Passive Reference dT(8)-AP593 **MRSA/SA Internal Control** Tris buffer <0.01% EDTA 0.01% total yeast RNA <0.001% Non-infectious plasmid DNA (recombinant) containing Internal Control sequences **MRSA/SA Positive Control** Tris buffer <0.01% EDTA 0.01% total yeast RNA <0.001% Non-infectious plasmid DNA (microbial) containing MRSA sequences	Same

Parameter	Test System Epoch Bioscience MRSA/SA ELITe MGB® using ELITe MGB® Software for data analysis	Predicate Device Epoch Bioscience MRSA/SA ELITe MGB® k112937
Specimen type	Direct from nasal swab	Same
Storage & Expiry	Stored in -20 °C freezer. The device is stable until the expiry date stated on the label.	Same
Instrument	ABI 7500 Fast Dx	Same
Controls	Positive PCR control (Plasmid DNA (microbial) containing MRSA sequences) Internal Control (Plasmid DNA (recombinant) containing Internal Control sequences)	Same

Differences

Parameter	Test System Epoch Bioscience MRSA/SA ELITe MGB® using ELITe MGB® Software for data analysis	Predicate Device Epoch Bioscience MRSA/SA ELITe MGB® k112937
Results interpretation	Automates the algorithm described in the labeling such that raw data from the Applied Biosytems 7500 FAST Dx instrument is calculated and the test result determined and printed on a report.	Uses an algorithm described in the labeling to determine test validity with respect to controls and then to determine the test result.

9. **Standard/Guidance Document Reference**
   - FDA Draft Guidance for Industry and Food and Drug Administration Staff Establishing the Performance Characteristics of Nucleic Acid-Based In vitro Diagnostic Devices for the Detection and Differentiation of Methicillin-Resistant *Staphylococcus aureus* (MRSA) and *Staphylococcus aureus* (SA), Issued January 5, 2011.
   - FDA Guidance for Industry, FDA Reviewers and Compliance on Off-the-Shelf Software Use in Medical Devices, Issued September 9, 1999.
   - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Document issued on: May 11, 2005.

10. **Test Principle:**

The test principle has not changed from that reviewed in k112937.

11. **Instrumentation/Software:**

a. Off the Shelf Software

The controls with respect to Off-the-Shelf software have not changed from those reviewed in k112937.

The system is performed with FDA-cleared devices, bioMérieux NucliSENS® easyMAG® extraction system and the Applied Biosystems® 7500 Fast Dx PCR Instrument. ELITechGroup Epoch Biosciences has a relationship with each on the manufacturers of these devices via service contracts such that Epoch will become aware, in the same time, as other users of the system, of changes to the device(s) or of the software used by the device(s). Internal quality assurance procedures are in place to verify the continued acceptable performance of the test device. Please, note, however, that the evaluation algorithm and the use of controls as indicated in the labeling, Internal Control and Positive Control, Negative Specimen Processing Control and Positive Specimen Processing Control, should identify for users any issues created by instrument or software changes.

b. Software to be used with this device

ELITech has developed a product, ELITe MGB® Software, fully in compliance with Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Document issued on: May 11, 2005. Information that substantiates this compliance are described. The software has a Moderate Level of Concern. The development of the software is in compliance with the requirements of the Guidance. The performance of the software has been validated.

11. **Performance Characteristics – Analytical Performance**

a. Analytical Sensitivity

No further studies were performed since k112937. The change to automate the calling algorithm using ELITe MGB® software will not affect this performance.

b. Analytical Reactivity

No further studies were performed since k112937. The change to automate the calling algorithm using ELITe MGB® software will not affect this performance.

c. Detection limit

No further studies were performed since k112937. The change to automate the calling algorithm using ELITe MGB® software will not affect this performance.

d. Reproducibility

No further studies were performed since k112937. The change to automate the calling algorithm using ELITe MGB® software will not affect this performance.

e. Carry-Over / Cross-Contamination

No further studies were performed since k112937. The change to automate the calling algorithm using ELITe MGB® software will not affect this performance.

12. **Performance Characteristics –**

a. Correlation with MRSA/SA ELITe MGB® manual calling algorithm

In accordance with guidance received from FDA in Q120176, the original data from k112937 was recalculated using ELITe MGB software.

Results of MRSA/SA ELITe MGB® using the ELITe MGB® Software exhibit 100% concordance with results of MRSA/SA ELITe MGB® using the manual calling algorithm found in the labeling for MRSA/SA ELITe MGB®.

b. Clinical Studies:

No further studies were performed since k112937. The change to automate the calling algorithm using ELITe MGB® software will not affect this performance.

c. Clinical Cut-off:

Not applicable

13. **Conclusion**

The information on the principle and performance of the test device contained in this premarket notification is complete and supports a decision that the test device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Elitechgroup Epoch Biosciences
Debra K. Hutson
Director, QA/RA, North America
21720 23rd Dr SE, Suite 150
Bothell, WA 98021 US

October 17, 2013

Re: k132468
Trade/Device Name: MRSA/SA ELITe MGB® Software
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Susceptibility Test Powder
Regulatory Class: II
Product Codes: NQX, NSU, JJH
Dated: August 5, 2013
Received: August 7, 2013

Dear Debra Hutson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Uwe Scherf -S for

Sally A. Hojvat, Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k132468

Device Name: MRSA/SA ELITe MGB®

Indications For Use:

MRSA/SA ELITe MGB® is a qualitative *in vitro* diagnostic test for the direct detection of *Staphylococcus aureus* (SA) and methicillin-resistant *Staphylococcus aureus* (MRSA) using DNA purified from nasal swabs. MRSA/SA ELITe MGB® is intended to aid in the prevention and control of MRSA infections in healthcare settings. It is not intended to diagnose, guide or monitor MRSA infections, or provide results of susceptibility to oxacillin/methicillin. A negative result does not preclude MRSA/SA *(Staphylococcus aureus*) nasal colonization. Concomitant cultures are necessary to recover organisms for epidemiological typing or for further susceptibility testing.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Ribhi Shawar -S
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